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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/575,689

05/21/2007

Colette Colladant

120164.417USPC

3581

500 7590 11/15/2010  
SEED INTELLECTUAL PROPERTY LAW GROUP PLLC  
701 FIFTH AVE  
SUITE 5400  
SEATTLE, WA 98104

EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1628

MAIL DATE

DELIVERY MODE

11/15/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/575,689	<b>Applicant(s)</b> COLLADANT ET AL.	
	<b>Examiner</b> Barbara P. Badio	<b>Art Unit</b> 1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-11 is/are pending in the application.
- 4a) Of the above claim(s) 3-6, 8 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 7, 9 and 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                          |

**Final Office Action on the Merits**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Status of the Application***

2. Claims 1 and 3-11 are pending in the present application. Claims 3-6, 8 and 11 stand withdrawn from further consideration as being drawn to a nonelected invention. Claims 1, 7, 9 and 10 stand rejected as indicated below.

***Claim Rejections - 35 USC § 112***

3. **The rejection of claim 2 under 35 USC 112, second paragraph is made moot by the cancellation of the instant claim.**

4. **The rejection of claims 1, 9 and 10 under 35 USC 112, second paragraph is withdrawn.**

5. **The rejection of claim 7 under 35 USC 112, second paragraph is maintained.**

The claim as amended recites dissolving the compound of formula (I) in methanol. However, the instant claim lacks identification of said compound of formula

(I). Thus, the skilled artisan in the art at the time of the present invention would have been unable to determine the metes and bound of the claimed invention.

For this reasons, the rejection of claim 7 under 35 USC 112, second paragraph is maintained.

### ***Double Patenting***

6. Claim 9 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Note: Both claims are drawn to “crystalline form A of 3 $\beta$ -amino-17-methylene-androstane-6 $\alpha$ ,7 $\beta$ -diol hydrochloride”. The recitation of the intended use of the compound in claim 9 does not limit the scope of the claimed compound.

### ***Claim Rejections - 35 USC § 102***

7. The rejection of claim 2 under 35 USC 102(b) over Raymond et al. (WO 01/83512 cited on IDS submitted by applicant on 5/21/2007) is made moot by the cancellation of the instant claim.

8. The rejection of claims 1, 9 and 10 under 35 USC 102(b) over Raymond et al. (WO 01/83512 cited on IDS submitted by applicant on 5/21/2007) is maintained.

Applicant argues (a) the examiner has not provided evidence that the claimed compound would necessarily result from the process as taught by Raymond, particularly in the absence of any teaching as to the physical form of the salts of the only related compound specifically prepared therein and (b) there is no clear case to show that the hydrochloride salt of 3 $\beta$ -amino-17-methylene-androstane-6- $\alpha$ ,7- $\beta$ -diol prepared by the teachings of Raymond would, in fact, be crystalline form A. Applicant's argument was considered but not persuasive for the following reasons.

If mere silence was enough, then every anticipation could be overcome by simply putting in some limitation that the reference happened to be silent about, even if the claimed compound is exactly the same as the prior art. Applicant has not provided any factual evidence showing that the hydrochloride salt of 3 $\beta$ -amino-17-methylene-androstane-6- $\alpha$ ,7- $\beta$ -diol prepared by the teachings of Raymond would differ from the presently claimed compound.

Raymond teaches the formation of the hydrochloride salt of 3 $\beta$ -amino-17-methylene-androstane-6- $\alpha$ ,7- $\beta$ -diol utilizing analogy synthesis as shown in Scheme E (see page 29, last paragraph; page 30, Scheme E). The process taught by Raymond comprises dissolving the hydrochloride salt of 3 $\beta$ -amino-17-methylene-androstane-6- $\alpha$ ,7- $\beta$ -diol in methanol, concentrating and triturating with acetone, followed by concentration to give a white solid (see page 63, last paragraph). As noted by Raymond, the crystallization process provided various polymorphic structures (see page 22, lines 26-33). The fact that the reference does not identify the specific form obtained does not imply that the compound is not exactly the same as the instantly claimed form.

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Applicant has not provided any evidence on record showing that the compound obtained by the process of Raymond differs from that of the instant claims.

In summary, Raymond anticipates the claimed compound via the teaching of a small genus of compounds that embraces the claimed compound and applicant has not provided evidence showing the claimed compound differ from the prior art compound. Mere silence of the exact form of the prior art compound does not imply said prior art compound differs from the instantly claimed compound.

For these reasons and those given in the previous Office Action, the rejection of claims 1, 9 and 10 under 35 USC 102(b) over Raymond et al. (WO 01/83512 cited on IDS submitted by applicant on 5/21/2007) is maintained

### ***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Telephone Inquiry***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Barbara P. Badio/  
Primary Examiner, Art Unit 1628